

Amendments to the Claims

1. (currently amended) A method of treating erectile dysfunction in a patient comprising administering a therapeutic amount of ~~an erectile dysfunction~~ a drug condensation aerosol to the patient by inhalation,

wherein the drug is selected from the group consisting of sildenafil, tadalafil and vardenafil, and wherein the condensation aerosol is formed by heating a thin layer containing the drug, on a solid support, to produce a vapor of the drug, and condensing the vapor to form a condensation aerosol characterized by less than 10% drug degradation products by weight, and having an MMAD of less than 3 μ m and less than 5% erectile dysfunction drug degradation products, to a patient by inhalation, upon activation by the patient of the formation of, and delivery of, the condensation aerosol 5 microns.

2. (currently amended) The method of according to claim 1, ~~wherein said condensation aerosol is formed by~~

~~—— a. —— volatilizing an erectile dysfunction drug under conditions effective to produce a heated vapor of the erectile dysfunction drug; and~~

~~—— b. —— condensing the heated vapor of erectile dysfunction drug to form condensation aerosol particles~~ wherein the condensation aerosol is characterized by an MMAD of less than 3 microns.

3. (currently amended) The method according to claim 2 1, ~~wherein said administration results in a peak plasma drug concentration of said erectile dysfunction drug is reached~~ in less than 0.1 hours.

4. (cancelled)

5. (currently amended) The method according to claim 3 1, wherein the ~~administered~~ condensation aerosol is formed at a rate greater than 0.5 mg/second.

6. (original) The method according to claim 1, wherein at least 50% by weight of the condensation aerosol is amorphous in form.

7 - 10. (cancelled)

11. (currently amended) The method according to claim 7 31, wherein ~~said the therapeutic amount of sildenafil condensation aerosol has an inhalable aerosol mass density of between 5 mg/L and 40 mg/L when delivered~~ comprises between 5 mg and 40 mg of sildenafil delivered in a single inspiration.

12. (currently amended) The method according to claim 7 32, wherein ~~said the therapeutic amount of tadalafil condensation aerosol has an inhalable aerosol mass density of between 2.5 mg/L and 20 mg/L when delivered~~ comprises between 2.5 mg and 20 mg of tadalafil delivered in a single inspiration.

13. (currently amended) The method according to claim 7 33, wherein ~~said the therapeutic amount of vardenafil condensation aerosol has an inhalable aerosol mass density of between 1 mg/L and 20 mg/L when delivered~~ comprises between 1 mg and 20 mg of vardenafil delivered in a single inspiration.

14. (currently amended) A method of administering ~~an erectile dysfunction drug to a patient to achieve a peak plasma drug concentration rapidly, comprising administering to the patient by inhalation an aerosol of an erectile dysfunction drug having less than 5% erectile dysfunction a drug~~ condensation aerosol to a patient by inhalation,

wherein the drug is selected from the group consisting of sildenafil, tadalafil and vardenafil, and
wherein the drug condensation aerosol is formed by heating a thin layer containing the drug, on a solid support, to produce a vapor of the drug, and condensing the vapor to form a condensation aerosol characterized by less than 10% drug degradation products and an MMAD of less than 3 microns 5 microns, and

wherein the peak plasma drug concentration of the erectile dysfunction drug is achieved is reached in less than 0.1 hours.

15. (cancelled)

16. (currently amended) A kit for delivering a drug condensation aerosol comprising:

a) ~~a.~~ a thin ~~coating of an erectile dysfunction drug composition and~~ layer containing the drug,
on a solid support, wherein the drug is selected from the group consisting of sildenafil, tadalafil and
varденаfil, and

b) ~~b.~~ a device for ~~dispensing said thin coating as a~~ providing the condensation aerosol,
wherein the condensation aerosol is formed by heating the thin layer to produce a vapor of the drug and
condensing the vapor to form a condensation aerosol characterized by less than 10% drug degradation
products by weight, and an MMAD of less than 5 microns.

17. (cancelled)

18. (currently amended) The kit of claim 16, wherein the device ~~for dispensing said coating~~
~~of an erectile dysfunction drug composition as an aerosol~~ comprises

(a) ~~a.~~ a flow through enclosure containing the solid support,

(b) ~~—~~ ~~contained within the enclosure, a metal substrate with a foil like surface and having a~~
~~thin coating of an erectile dysfunction drug composition formed on the substrate surface,~~

(e) ~~b.~~ a power source that can be activated to heat the ~~substrate to a temperature effective to~~
~~volatilize the erectile dysfunction drug composition contained in said coating, and~~ solid support, and

(d) ~~c.~~ inlet and exit portals at least one portal through which air can be drawn through said
device by inhalation,

wherein ~~heating the substrate by activation of the power source is effective to form an erectile~~
~~dysfunction drug vapor containing less than 5% erectile dysfunction drug degradation products, and~~
~~drawing air through said chamber is effective to condense the erectile dysfunction drug vapor to form~~
~~aerosol particles wherein the aerosol has an MMAD of less than 3 microns~~ produce a vapor of the drug,
and drawing air through the enclosure is effective to condense the vapor to form the condensation
aerosol.

19. (currently amended) The kit according to claim 18, wherein the heat for heating the
~~substrate~~ solid support is generated by an exothermic chemical reaction.

20. (currently amended) The kit according to claim 19, wherein ~~said the~~ the exothermic
chemical reaction is oxidation of combustible materials.

21. (currently amended) The kit according to claim 18, wherein the heat for heating the ~~substrate~~ solid support is generated by passage of current through an electrical resistance element.

22. (currently amended) The kit according to Claim 18, wherein said ~~substrate~~ solid support has a surface area dimensioned to accommodate a therapeutic dose of ~~an erectile dysfunction drug~~ the drug composition in said coating the drug.

23. (currently amended) The kit according to claim 16, ~~wherein a peak~~ wherein peak plasma concentration of ~~erectile dysfunction drug is obtained~~ the drug is reached in less than 0.1 hours ~~after delivery of the condensation aerosol to the pulmonary system~~.

24. (original) The kit of claim 16, further including instructions for use.

25. (new) The method according to claim 1, wherein the condensation aerosol is characterized by an MMAD of 0.2 to 5 microns.

26. (new) The method according to claim 2, wherein the condensation aerosol is characterized by an MMAD of 0.2 to 3 microns.

27. (new) The method according to claim 1, wherein the condensation aerosol comprises at least 80% drug by weight.

28. (new) The method according to claim 27, wherein the condensation aerosol comprises at least 95% drug by weight.

29. (new) The method according to claim 1, wherein the thin layer comprises at least 80% drug by weight.

30. (new) The method according to claim 29, wherein the thin layer comprises at least 95% drug by weight.

31. (new) The method according to claim 1, wherein the drug is sildenafil.
32. (new) The method according to claim 1, wherein the drug is tadalafil.
33. (new) The method according to claim 1, wherein the drug is vardenafil.
34. (new) The kit according to claim 16, wherein the condensation aerosol is characterized by an MMAD of less than 3 microns.
35. (new) The kit according to claim 16, wherein the condensation aerosol is characterized by an MMAD of 0.2 to 5 microns.
36. (new) The kit according to claim 34, wherein the condensation aerosol is characterized by an MMAD of 0.2 to 3 microns.
37. (new) The kit according to claim 16, wherein the condensation aerosol comprises at least 80% drug by weight.
38. (new) The kit according to claim 37, wherein the condensation aerosol comprises at least 95% drug by weight.
39. (new) The kit according to claim 16, wherein the thin layer comprises at least 80% drug by weight.
40. (new) The kit according to claim 39, wherein the thin layer comprises at least 95% drug by weight.
41. (new) The kit according to claim 16, wherein the drug is sildenafil.
42. (new) The kit according to claim 16, wherein the drug is tadalafil.

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43. (new) The kit according to claim 16, wherein the drug is vardenafil.
44. (new) The kit according to claim 18, wherein the solid support has a surface to mass ratio of greater than 1 cm² per gram.
45. (new) The kit according to claim 18, wherein the solid support has a surface to volume ratio of greater than 100 per meter.
46. (new) The kit according to claim 18, wherein the solid support is a metal foil.
47. (new) The kit according to claim 46, wherein the metal foil has a thickness of less than 0.25 mm.